

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

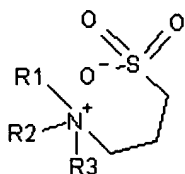
Claim 1 (original) A pharmaceutical composition which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine (NDSB).

Claim 2 (original) The pharmaceutical composition according to claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of a therapeutically effective synthetic or natural organic molecule and a therapeutically effective protein.

Claim 3 (original) The pharmaceutical composition according to claim 2, wherein the therapeutically effective protein is selected from the group consisting of granulocyte-colony stimulating factor, interferons, interleukins, granulocyte-macrophage colony-stimulating factor, macrophage colony-stimulating factor, epidermal growth factor, erythropoietin, follicle-stimulating hormone, human serum albumin, deoxyribonuclease, fibroblast calcitonin, hematoprotein; plasminogenic activators and their precursors, cytokines; TNF family of ligands, soluble receptors, growth hormones, lipoproteins; alpha-1-antitrypsin; insulin, proinsulin, subunit A of insulin, subunit B of insulin; glucagons; blood coagulation factors, bombasine; thrombin; enkephalinase; macrophage inflammatory protein (MIP-1-alpha); relaxin A subunit, relaxin B subunit, prorelaxin; inhibin; activin; vascular endothelial growth factor; hormone receptors or growth factor receptors; integrins; protein A, protein D; rheumatoid factors; bone-derived neurotrophic factor, neurotrophin-3,-4,-5, or -6; nerve growth factor, platelet-derived growth factor, fibroblast growth factor, transformed growth factor, insulin-like growth factor, thrombopoietin, bone morphogenetic protein and superoxide dismutase.

Claim 4 (original) The pharmaceutical composition according to claim 3, wherein the therapeutically effective protein is G-CSF.

Claim 5 (currently amended)The pharmaceutical composition according to ~~any of the preceding claims~~ claim 1, wherein the NDSB is quaternary ammonium salt of Formula 1,



Formula 1

wherein R1, R2 and R3 can be the same and/or different and are selected from the group consisting of methyl, ethyl, propyl, butyl, pentyl, hexyl or their derivatives, and R4 is $(CH_2)_n$, wherein n is between 1 and 6.

Claim 6 (original) The pharmaceutical composition according to claim 5, wherein the NDSB is selected from the group consisting of dimethylethyl-(3-sulphopropyl)-ammonium salt, 3-(1-pyridino)-1-propanesulfonate, dimethylbenzylammonium propanesulfonate, dimethyl-t-butyl-(3-sulphopropyl) ammonium salt, 3-(1-methylpiperidine)-1-propanesulfonate and dimethyl-(2-hydroxyethyl)-(sulphopropyl)-ammonium salt.

Claim 7 (original) The pharmaceutical composition according to claim 6, wherein the NDSB is dimethyl-t-butyl-(3-sulphopropyl) ammonium salt.

Claim 8.(currently amended)The pharmaceutical composition according to ~~claims 1 to 7~~ claim 1 wherein said composition optionally further comprises a polyol.

Claim 9. (original) The pharmaceutical composition according to claim 8, wherein the polyol is selected from the group consisting of sorbitol, glycerol, inositol, trehalose and mannitol.

Claim 10 (currently amended) The pharmaceutical composition according to ~~claims 1 to 9~~ claim 1, wherein said composition optionally further comprises one or more pharmaceutically acceptable excipients.

Claim 11 (original) The pharmaceutical composition according to claim 10, wherein a pharmaceutically acceptable excipient is selected from the group consisting of EDTA and DMSO.

Claim 12 (currently amended) A process for preparation of a pharmaceutical composition, wherein ~~said a pharmaceutical composition~~ of claim 1 is prepared by mixing a NDSB with therapeutically effective amount of an active pharmaceutical ingredient.

Claim 13 (cancelled) Use of a NDSB for the preparation of a pharmaceutical composition.

Claim 14 (currently amended) ~~Use of~~ A method of using a NDSB as a stabiliser in a pharmaceutical composition.

Claim 15 (currently amended) ~~Use of~~ A method of using a NDSB as a buffering agent in a pharmaceutical composition.

Claim 16 (currently amended) ~~Use of~~ A method of using a NDSB as a pH adjusting agent in a pharmaceutical composition.